

**REMARKS/ARGUMENTS**

This is a response to the Office Action dated February 3, 2003. Reconsideration of the claims based on the remarks provided below is respectfully requested. Claim 23 has been amended and claims 63 to 148 have been added.

Applicant appreciates the Examiner's identification of the informal error in claim 31 and have amended claim 31 accordingly.

The Examiner rejected claims 1-20, 25-50 and 52-62 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al. in view of U.S. Patent No. 6,171,112 to Clark et al. Claims 1, 25 and 31 are independent. Regarding claim 1, the Examiner asserts that Colon teaches the claim 1 element "the release of at least one of medical and personal information" based on "the [Colon] system captur[ing] data in its database through appropriate input forms developed for the specific clinical study and [storing the data] online and [producing reports] in real time to study investigators." However, as the Examiner asserts, Colon does not teach the claim 1 element "receiving over a network from a computer terminal an individual's on-line consent to an electronic agreement." For this teaching, the Examiner relies on Clark by asserting that Clark teaches "authenticating informed consent for a patient that includes providing a means for the patient to input data in the form of answers to questions as well as prompting the patient for electronic signature."

Regarding Colon, the Examiner appears to argue that data entry into the system, processing of the data including the production of reports and transmission to users of the system teaches the claim 1 recitation "release of at least one of medical and personal information." However, this recitation of claim 1 is within the context of an individual's on-line consent to such release. Mere personal or medical data entry for release into a system or processing of such data for release in a report takes the claim 1 recitation out of context because claim 1 requires that the individual to which the personal and medical information is attributed to has to provide his consent for such release.

In addition, Colon explicitly provides that "online data entry is restricted to authorized users

only and data transmissions may be encrypted to ensure confidentiality.” (Colon, col. 2, ll. 21-23.) Authorized users include employees of the participating clinical sites (Colon, abstract), e.g., clinical study investigators (Colon, col. 1, ll. 36-39) and doctors (Colon, col. 1, ll. 43-47). Colon also described that the system and method are based on “each participating clinical site having a computer for inputting, transmitting and receiving data over the Internet.” (Colon, abstract.) Individuals to which the personal or medical data is attributed are not authorized users of the system and therefore cannot provide on-line consent to the release of such data to the system. Therefore, the Colon system cannot support an individual providing an electronic signature because individuals are not authorized users of the Colon system.

In addition, Clark does not teach an individual providing an electronic signature for releasing personal or medical information. Rather, Clark involves an individual’s electronic signature for informed consent (Clark, abstract.) Therefore, there is no cited reference which teaches an individual providing an electronic signature for the release of personal or medical information. Moreover, these references can not be combined to provide such a teaching because even if the Clark electronic signature teaching is applied to Colon, the Colon system prohibits the individual to whom the personal and medical information is attributed from communicating with the system. As a result, the Colon system specifically precludes an electronic signature by the individual for the release of the individual’s personal or medical information.

Each of the remaining independent claims 25 and 31 and likewise the claims which depend from them recites the same subject matter as discussed above for claim 1. Therefore, neither Colon nor Clark teaches explicitly or implicitly claims 1, 25, 31 and their depending claims and the references cannot be combined to provide such a teaching. Applicant accordingly respectfully requests that these rejections be withdrawn.

The Examiner also rejected claims 21, 24 and 51 under 35 U.S.C. 103(a) as being unpatentable over Colon and Clark in view of an Official Notice. Each of these claims are dependent on claims which, as argued above, are patentable in view of Colon or Clark and the references cannot be combined to provide such teaching. In addition, the Official Notice is unrelated to the patentable subject matter. Applicant accordingly respectfully requests that these

rejections be withdrawn.

Claims 22-23 were also rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Colon and Clark in view of U.S. Patent No. 6,272,470 to Teshima. Each of these claims is dependent on claims which, as argued above, are patentable in view of Colon in combination with Clark. In addition, Teshima does not teach the patentable subject matter which is not taught by Colon in combination with Clark. Applicant accordingly respectfully requests that these rejections be withdrawn.

Applicant added claims 63-152. Support for the claims is as follows:

claim 63, originally filed claim 3 and page 3, lines 11-13; claim 64, page 9, lines 10-19; claim 65, page 9, lines 10-19; claim 66, page 6, lines 12-18; claim 67 (see claim 63); claim 68 (see claim 66); claim 69 (see claim 63); claim 70 (see claim 64); claim 71 (see claim 65); claim 72 (see claim 66); claim 73, originally filed claim 1 and page 8, line 23 to page 9, line 19; claim 74, page 8, line 23 to page 9, line 19; claim 75, originally filed claim 2; claim 76 and 77, originally filed claim 3; claims 78 to 89, originally filed claims 4 to 15, respectively; claim 90 (see claim 64); claim 91 (see claim 65); claim 92 to claim 100, originally filed claims 16 to 24, respectively; claim 101 (see claim 66); claim 102, originally filed claim 1; claims 103, originally filed claim 2; claims 104 to 105, originally filed claim 3; claims 106 to 117, originally filed claims 4 to 1, respectively; claim 118 (see claim 64); claim 119 (see claim 65); claims 120 to 128, originally filed claims 16 to 24, respectively; claim 129 and 130 (see claim 66); claim 131 and 132, originally filed claim 1; claim 133, originally filed claim 1 and page 4, line 25 to page 5, line 5; claim 133, originally filed claim 7; claim 134, originally filed claim 1; claim 135 (see claim 74); claim 136, originally filed claim 1; claim 137 (see claim 130); claim 138 and 139, originally filed claim 1; claim 140 (see claim 66); claim 141, originally filed claim 1; claim 142, originally filed claim 7; claim 143, originally filed claim 1; claim 144, originally filed claims 1 and 3 and page 4, line 25 to page 5, line 14; claim 145, originally filed claims 1 and 3 and page 4, line 25 to page 5, line 14; claim 146, originally filed claim 7; claim 147, page 8, line 23 to page 9, line 9; claim 148 (see claim 64).

Since each of the new independent claims and likewise the claims which depend from them recite the same patentable subject matter as claims 1, 25 and 31 discussed above, the

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combination of Colon and Clark do not teach the new independent claims and likewise the claims which depend from them. Applicants therefore respectfully request that the new claims be allowed and passed to issue.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

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Respectfully submitted,

By Cheryl Bab

Cheryl Milone Bab

Registration No.: 43,480

DARBY &amp; DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 753-6237 (Fax)

Attorney for Applicant